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PATENT

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Assistant Commissioner for Patents
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Washington, D.C. 20231

REISSUE APPLICATION TRANSMITTAL
(Broadening Reissue)

Transmitted herewith is the application for reissue of:

U.S. Patent No.:5,554,121

issued on: September 10, 1996

Inventor(s): Robert D. Ainsworth, Tai C. Cheng and Lawrence D. Wasicek.

Title: INTRALUMINAL CATHETER WITH HIGH STRENGTH PROXIMAL SHAFT

The patentee hereby requests that the U.S. Patent identified above be reissued to correct the errors identified and to be identified in the original patent, as indicated in the enclosed specification and claims.

This application for a broadening reissue is being filed on or before September 10, 1998 – the second anniversary of the issue date of the patent.

Enclosed are the following:

1. **Specification:**
   An amended specification (7 pages), with additions and deletions indicated by bracketing and underlining;

2. **Claims:**
   - Original claims 1-6,
   - claims 7-17 added by Reexamination Certificate B1 (3574th) on Jul. 14, 1998, as amended, and
   - new claims 18-56 added in this reissue application;

3. **Drawings:**

1 sheet of original drawing (formal);

4. **Abstract:**

An amended Abstract on 1 sheet; and

5. **Printed Patent:**

A copy of the original printed patent and reexamination certificate.

The following papers or items are <u>not enclosed</u>, and will be supplied later

6. **Declaration and power of attorney**

7. The written **consent of the assignees** to the reissue

8. **A submission demonstrating the ownership interest of the assignee,** in accordance with the provisions of 37 CFR § 3.73(b).

9. An **Offer to surrender** the original letters patent

10. The necessary **fee.**

11. An **Information Disclosure Statement** and enclosures.

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FORM 401

NOTICE OF FILING OF REISSUE APPLICATION FOR PUBLICATION IN OFFICIAL GAZETTE

ORIGINAL PATENT NUMBER	5554121
SERIAL NUMBER OF REISSUE	09/143503
FILING DATE	8-28-98
CLASS AND SUBCLASS	604/96
TITLE	INTRALUMINAL CATHETER WITH HIGH STRENGTH PROXIMAL SHAFT
INVENTOR	ROBERT D AINSWORTH et al
OWNER OF RECORD	ADVANCED CARDIOVASCULAR SYSTEMS INC. SANTA CLARA, CA
ATTORNEY OR AGENT OF RECORD	GEORGE WHEELER
EXAMINING GROUP ASSIGNED	
DATE OF ANNOUNCEMENT IN OFFICIAL GAZETTE	

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SPECIFICATION AND CLAIMS FOR REISSUE APPLICATION

U.S. Patent No. 5,554,121

Issued Sep. 10, 1996

TITLE:

Intraluminal catheter with high strength proximal shaft

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Issued from U.S. Serial No.: 280,210

Filed: Jul. 25, 1994

Primary Examiner: Yasko, John D.

Assistant Examiner: Knights, Laird J.

BACKGROUND OF THE INVENTION

This invention relates to the field of intravascular catheters, and more particularly to a dilatation catheter for percutaneous transluminal coronary angioplasty (PTCA).

PTCA is one of the most widely used treatment modalities for heart disease. The procedure basically comprises advancing a dilatation catheter, having an inflatable balloon on the distal portion thereof, into the patient's coronary anatomy until the balloon of the dilatation catheter is properly positioned across the lesion to be dilated. Once properly positioned, the dilatation balloon is inflated with liquid one or more times to a predetermined size at relatively high pressures (e.g. greater than 4 atmospheres) to expand the arterial passageway. Generally, the inflated diameter of the balloon is approximately the same diameter as the native diameter of the body lumen being dilated so as to complete the dilatation but not overexpand the artery wall. After the balloon is finally deflated, blood flow resumes through the dilated artery and the dilatation catheter can be removed therefrom.

Commercially available over-the-wire dilatation catheters for angioplasty and other vascular procedures usually comprise an elongated shaft with an inflatable dilatation member on a distal portion of the shaft and an adapter on the proximal end of the shaft for the delivery of inflation fluid through an inner lumen extending through the catheter shaft to the interior of the inflatable dilatation member. A second inner lumen configured to slidably receive a guidewire extends through the shaft to a guidewire port in the distal end of the catheter. Conventional over-the-wire catheters have the guidewire receiving inner lumen[§] extending from the proximal end of the catheter to the distal end of the catheter. A catheter configured for rapid exchange has a much shorter guidewire lumen and extends from a proximal guidewire port spaced a substantial distance from the proximal end of the catheter to the distal port in the distal end.

The progression of improvements in dilatation catheters generally has been to make the catheters with lower profiles, i.e. smaller transverse dimensions, and with [the] stiffer proximal shafts. A stiffened proximal shaft provides greater push to the catheter which facilitates advancement over a guidewire in tortuous anatomy. Stiffened proximal shaft sections formed of plastic materials, stainless steel and superelastic NiTi alloys are disclosed in the prior art. However, the raw material and manufacturing costs for a catheter having a relatively stiff proximal shaft is quite high.

What has been needed is an [intraluminal] intraluminal catheter which has a low profile and a relatively stiff proximal shaft which is easy and inexpensive to manufacture. The present invention provides such a desirable product.

SUMMARY OF THE INVENTION

This invention is directed to an intraluminal catheter which has at least part of the shaft thereof formed of a melt processable engineering thermoplastic polymer material and preferably an aromatic polymer. The melt processed, e.g. extruded, thermoplastic polymer has a tensile strength greater than 10,000 psi (6895 N/cm^2), preferably greater than 14,000 psi (9653 N/cm^2), an elongation at break greater than 50%, preferably greater than 60%, and a tensile modulus greater than 300,000 psi (206,850 N/cm^2), preferably greater than 400,000 psi (275,800 N/cm^2). The melt processable linear aromatic polymers include [including] polyetheretherketone (PEEK), polyetherketone, polyketone, polyethereketoneketone, polyaryletherketone, polysulfone and polyether sulfone. Other aromatic engineering thermoplastic polymers which have the above properties are also suitable.

One presently preferred embodiment of the invention is a dilatation catheter which has an elongated catheter shaft with a relatively stiff proximal portion formed of the engineering thermoplastic polymer and a relatively flexible distal portion and an inflatable dilatation member on the distal portion of the catheter. The proximal portion of the presently

preferred embodiment has an outer tubular member, an inner tubular member disposed within the outer tubular member and defining an annular inner lumen between the inner and outer tubular [member] members. The inner tubular member has an inner lumen which extends to a distal guidewire port in the distal end thereof. At least one of the inner and outer tubular members forming the proximal portion of the catheter shaft [are] is formed of the engineering thermoplastic polymer described above.

In this embodiment, the distal portion of the inflatable dilatation member is sealed about and secured to a distal extremity of the inner tubular member and the proximal portion of the inflatable dilatation member is sealed about and secured to a distal extremity of the outer tubular member.

The intraluminal catheter of the invention has excellent pushability due to the relatively stiff proximal portion, yet because the requisite aromatic polymers can be formed into very thin walled structures and have relatively high strength and elongation properties, the catheter shafts generally do not kink under normal intraluminal use. These and other advantages of the invention will become more apparent from the following detailed description of the invention and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view partially in section of a dilatation catheter assembly which embodies features of the invention.

FIG. 2 is a longitudinal cross-sectional view of the shaft of the catheter assembly shown in circle 2 shown in FIG. 1.

FIG. 3 is a transverse cross-sectional view of the shaft shown in FIG. 2, taken along the lines 3-3.

DETAILED DESCRIPTION OF THE INVENTION

As shown in FIG. 1 the dilatation catheter 10 of the invention generally includes an elongated catheter shaft 11 with an inflatable

dilatation balloon 12 on a distal portion of the catheter shaft and an adapter 13 mounted on the proximal end of the catheter shaft.

The catheter shaft 11 has an outer tubular member 14 and an inner tubular member 15 disposed within the outer tubular member and defining with the outer tubular member an annular lumen 16 which is in fluid communication with the interior of the inflatable dilatation balloon 12. The inner tubular member 15 has an inner lumen 17 extending therein which is configured to slidably receive a guidewire 18 suitable for advancement through a patient's coronary arteries.

The distal extremity of the inflatable dilatation balloon 12 is sealingly secured to the distal extremity of the inner tubular member 15 and the proximal extremity of the balloon is secured to the distal extremity of the outer tubular member 16.

The outer tubular member 16 has a relatively stiff proximal portion 20 formed of a [requisite] linear aromatic polymer and the distal extremity of the proximal portion 20 is secured to the proximal extremity of the distal portion 21 of the outer tubular member at a lap joint 22 formed by suitable means such as heat or laser fusion or commercially available cyanoacrylate adhesives. The distal portion 21 of the outer tubular member 14 is formed of a melt processable more flexible polymer material such as polyethylene or Hytrel® [Registered TM]. The inner tubular member 15 extends along the entire length of the catheter and may be formed of suitable materials such as polyethylene, Hytrel® [Registered TM] and the like.

The length of the dilatation catheter 10 may be about 120 to about 150 cm [in length], and typically is about 135 cm [in length]. The outer tubular member 15 has an outer diameter (OD) [OD] of about 0.03 to about 0.05 inch (0.76-1.27 mm) and an inner diameter (ID) [ID] of about 0.025 to about 0.035 inch (0.635-0.899 mm). Although not shown in the drawings, the outer tubular member 14 may taper in its distal portion to a smaller OD of about 0.04 to about 0.02 inch (1.02-10.5 mm) and a smaller ID of about 0.03 to about 0.015 inch [](0.762-0.381). The smaller diameter portion

between the taper and the proximal extremity of the balloon 12 may be about 5 to about 25 cm in length.

The inner tubular member 15 has an OD ranging from about 0.018 to about 0.026 inch (0.457-0.66 mm), and the ID of the inner tubular member will usually be determined by the diameter of the guidewire 18 which is to be used with the catheter, which may range from about 0.008 to about 0.02 inch [(](0.203-0.51 mm). The inner diameter of the inner lumen should be about 0.002 to about 0.005 (0.051-0.127 mm) inch larger than the OD of the guidewire 18 to be used. Usually there will be a family of catheters for each size of guidewire with a variety of maximum inflated balloon sizes, e.g. 0.5 to about 4 mm in diameter and with various working lengths ranging from about 1 to about 10 cm.

In a presently preferred embodiment the proximal portion 20 of the outer tubular member 16 is formed of PEEK (Grade 381 G) from Victrex USA. The resin is readily extruded at a temperature of about 750° to about 800° F. at a pressure of about 2800 psi into thin walled tubing suitable for the outer tubular member forming the proximal portion of the catheter shaft. The proximal end of the distal portion of the outer tubular member is plasma treated to facilitate the joining of the distal end of the extruded tubular member to the proximal end of the distal portion of the outer tubular member 16. The proximal end of the distal portion 21 of the outer tubular member 16 is secured by a suitable adhesive in a lap joint at least about 1 mm and preferably about 2 to about 4 mm in length to the distal end of the distal portion 21 of the outer tubular member 16. The adhesive is preferably a UV cured adhesive such as UV 350 which is available from the Loctite Corporation, although other conventional adhesives are suitable.

In another preferred embodiment of the invention inner tubular member 15 is preferably of composite construction comprising a polymer such as polyethylene or Hytrel® [Registered TM] which has incorporated therein graphite particles, such as described in copending application Ser. No. 08/134,863, filed on Oct. 12, 1993, entitled COMPOSITE MATERIAL

HAVING A LUBRICOUS SURFACE FOR CATHETER USE, and a copending application [filed concurrently herewith], Ser. No. 08/280,291, filed Jul. 26 1994, now abandoned, entitled: COMPOSITE POLYESTER MATERIAL HAVING A LUBRICOUS SURFACE, both of which are incorporated herein in their entirety. Both [application] applications are assigned or will be assigned to the present assignee, Advanced Cardiovascular Systems, Inc.

To the extent not previously described herein, the various catheter components may be formed of conventional materials. For example, the radiopaque marker 31 may be a gold band and the adapter body may be formed of polycarbonate polymer[s]. The balloon 12 may be a relatively inelastic high strength material such as polyethylene, polyethylene terephthalate, polyolefinic ionomers such as Surlyn® [Registered TM], nylon and the like which are frequently used to form dilatation balloons.

While the present invention has been described herein primarily in terms of a catheter construction wherein the proximal portion of the outer tubular member is formed of the requisite linear aromatic polymer, those skilled in the art will recognize that the proximal portion or the entire inner tubular member may be formed of a linear aromatic polymer. Moreover, a portion of the catheter shaft can have an extruded dual lumen construction which is formed of a linear aromatic polymer. Other modifications and improvements may be made to the invention [with out] without departing from the scope thereof.

CLAIMS:

What is claimed is:

1. A balloon dilatation catheter comprising:

a) a proximal catheter shaft portion formed at least in part of an extruded engineering thermoplastic polymeric material with a tensile strength greater than 10,000 psi, an elongation greater than 50% and a tensile modulus greater than 300,000 psi, having proximal and distal ends and having a first inner lumen extending therein to the distal end;

b) a distal catheter shaft portion being more flexible than the proximal catheter shaft portion, having proximal and distal ends and a second inner lumen extending from the proximal end of the distal shaft portion to a location proximal to the distal end of the distal catheter shaft portion and being in fluid communication with the first inner lumen extending within the proximal catheter shaft portion; and

c) an expandable dilatation balloon on the distal catheter shaft portion having an interior in fluid communication with the second inner lumen extending within the distal shaft portion.

2. The balloon dilatation catheter of claim 1 wherein the polymeric material is a linear aromatic polymer.

3. The balloon dilatation catheter of claim 2 wherein the linear aromatic polymer is selected from the group consisting of polyetheretherketone, polyetherketone, polyketone, polyethereketoneketone, polyaryletherketone, polysulfone and polyether sulfone.

4. The balloon dilatation catheter of claim 1 wherein the polymeric material of the proximal catheter shaft has a tensile strength greater than about 14,000 psi, an elongation greater than about 60% and a tensile modulus greater than about 400,000 psi.

5. The balloon dilatation catheter of claim 1 wherein the proximal catheter shaft portion has an outer tubular member and an inner tubular member which is disposed within the outer tubular member and which defines with the outer tubular member the first inner lumen extending therein, at least one of the inner and the outer tubular members being formed of the extruded engineering thermoplastic polymeric material.

6. The balloon dilatation catheter of claim 1 wherein the relatively stiff proximal catheter shaft portion includes a relatively flexible distal shaft portion.

7. The balloon dilatation catheter of claim 1, wherein the polymeric material is a polyetheretherketone.

8. The balloon dilatation catheter of claim 4, wherein the polymeric material is a polyetheretherketone.

9. The balloon dilatation catheter of claim 5, wherein the polymeric material is a polyetheretherketone.

10. The balloon dilatation catheter of claim 6, wherein the polymeric material is a polyetheretherketone.

11. The balloon dilatation catheter of claim 1, wherein the proximal catheter shaft portion includes an outer tubular member made of the polymeric material.

12. The balloon dilatation catheter of claim 11, wherein the proximal material is a polyetheretherketone.

13. The balloon dilatation catheter of claim 5, wherein the outer tubular member is made of the polymeric material.

14. The balloon dilatation catheter of claim 13, wherein the polymeric material is a polyetheretherketone.

15. The balloon dilatation catheter of claim 1, wherein:

[A] a) the polymeric material is a polyetheretherketone having a tensile strength greater than about 14,000 psi, an elongation greater than about 60 and a tensile modulus greater than about 400,000 psi; and

[B] b) the proximal catheter shaft portion has an outer tubular member and an inner tubular member which is disposed within the outer tubular member and which defines with the outer tubular member the first inner lumen extending therein, at least one of the inner and the outer tubular members being formed of the polyetheretherketone.

16. The balloon dilatation catheter of claim 1 sized and having the flexibility and, pushability required for use as a dilatation catheter for percutaneous transluminal coronary angioplasty.

17. The balloon dilatation catheter of claim 16, wherein the polymeric material is a polyetheretherketone.

18. An intraluminal catheter for percutaneous insertion and transluminal advancement into a patient's vasculature, the catheter having a shaft comprising:

a) a proximal shaft portion formed at least in part of an extruded thermoplastic polymeric material with a tensile strength greater than 10,000 psi; and

b) a distal shaft portion that is more flexible than the proximal shaft portion.

19. The catheter of claim 18, wherein the polymeric material is a polyetheretherketone.

20. The intraluminal catheter of claim 18, wherein the extruded thermoplastic polymeric material has an elongation greater than 50%.

21. The catheter of claim 20, wherein the polymeric material is a polyetheretherketone.

22. The catheter of claim 18, further comprising a lumen extending at least in the distal shaft portion.

23. The catheter of claim 22, further comprising a second lumen in the catheter shaft adapted to receive a guidewire, the second lumen extending from a distal port in the distal end of the catheter to a proximal guidewire port proximal of the distal guidewire port.

24. The catheter of claim 22, further comprising an expandable dilatation balloon carried by the shaft, wherein the lumen directs inflation fluid to the dilatation balloon.

25. The catheter of claim 24, wherein the lumen has a proximal end for receiving inflation fluid and a distal end for directing inflation fluid to the balloon.

26. The catheter of claim 18, wherein the shaft has an inner tubular member and an outer tubular member, at least one of the inner and the outer tubular members having a proximal portion formed of the extruded thermoplastic polymeric material.

27. The catheter of claim 26 wherein the polymeric material is a polyetheretherketone.

28. The catheter of claim 26, wherein the proximal portion of the outer tubular member is made of the extruded thermoplastic polymeric material.

29. The catheter of claim 28 wherein the extruded thermoplastic polymeric material is a polyetheretherketone.

30 The catheter of claim 28, wherein a distal portion of the outer tubular member is made of a material more flexible than the extruded thermoplastic polymeric material.

31. The catheter of claim 18, wherein the extruded thermoplastic polymeric material has a tensile modulus greater than 300,000 psi.

32. The catheter of claim 31, wherein the polymeric material is a polyetheretherketone.

33. The catheter of claim 18, wherein the extruded thermoplastic polymeric material has a tensile modulus greater than about 400,000 psi.

34. The catheter of claim 33, wherein the polymeric material is a polyetheretherketone.

35. The catheter of claim 18, wherein the extruded thermoplastic polymeric material has a tensile strength greater than about 14,000 psi.

36. The catheter of claim 35, wherein the polymeric material is a polyetheretherketone.

37. The catheter of claim 18, wherein the extruded thermoplastic polymeric material has an elongation greater than about 60%.

38. The catheter of claim 37, wherein the polymeric material is a polyetheretherketone.

39. The catheter of claim 18, wherein the polymeric material has an elongation greater than 50% and a tensile modulus greater than 300,000 psi.

40. The catheter of claim 39, wherein the polymeric material is a polyetheretherketone.

41. The catheter of claim 18, wherein the polymeric material is a polyetheretherketone having a tensile strength greater than about 14,000 psi, an elongation greater than about 60%, and a tensile modulus greater than about 400,000 psi.

42. The catheter of claim 41, wherein the polymeric material is a polyetheretherketone.

43. The catheter of claim 18, sized and having the flexibility and pushability required for percutaneous transluminal coronary angioplasty.

44. The catheter of claim 43, wherein the polymeric material is a polyetheretherketone.

45. The catheter of claim 18, sized and having the kink-resistance required for percutaneous transluminal coronary angioplasty.

46. The catheter of claim 45, wherein the polymeric material is a polyetheretherketone.

47. The catheter of claim 18, sized and having the flexibility, pushability, and kink-resistance required for percutaneous transluminal coronary angioplasty.

48. The catheter of claim 47, wherein the polymeric material is a polyetheretherketone.

49. The catheter of claim 18, wherein the shaft is about 120 to about 150 cm in length.

50. The catheter of claim 49, wherein the polymeric material is a polyetheretherketone.

51. The catheter of claim 18, wherein the proximal shaft portion comprises an extruded tubular member of the extruded thermoplastic polymeric material.

52. The catheter of claim 51, wherein the polymeric material is a polyetheretherketone.

53. An intraluminal catheter for percutaneous insertion and transluminal advancement into a patient's vasculature, the catheter having a shaft comprising:

a) a proximal shaft portion formed at least in part of an extruded thermoplastic polymeric material with a tensile modulus greater than 300,000 psi; and

b) a distal shaft portion that is more flexible than the proximal shaft portion.

54. The catheter of claim 53, wherein the polymeric material is a polyetheretherketone.

55. The catheter of claim 53, wherein said extruded thermoplastic polymeric material has an elongation greater than 50%.

56. The catheter of claim 55, wherein the polymeric material is a polyetheretherketone.